

**ARIZONA DEPARTMENT OF
HEALTH SERVICES**

**BUREAU OF NUTRITION &
PHYSICAL ACTIVITY**



LABORATORY PROCEDURE MANUAL

9th Edition
Revised: March 2014

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Chapter 1. Introduction

Purpose

The purpose of the Arizona Department of Health Services, Bureau of Nutrition & Physical Activity Laboratory Procedure Manual is to provide guidance to local agency staff while performing hemoglobin tests used in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), the Commodity Supplemental Food Program (CSFP) and the Community Nutrition Programs. The manual is designed to be user-friendly.

Effective January 1, 2010, the Arizona WIC Program has transitioned to the HemoCue® 201+ analyzers. HemoCue 201+ analyzers are the primary measurement method for hemoglobin status in children under 2 years old who require screening for anemia. HemoCue® 201+ analyzers require a small blood sample size, do not track or store data, and have an internal electronic self-test. The self-test verifies the performance of the optronic unit and is performed every second hour that the machine is on.

Beginning in September 2012 Arizona WIC introduced the Masimo Pronto Pulse CO-Oximeter as the primary measurement method for hemoglobin status in adults and children 2 years and older. It replaces the HemoCue analyzer for all WIC participants at least 2 years old except for circumstances when a reading cannot be obtained using the Pronto. The Pronto has been cleared for use in the clinical setting by FDA because it is both accurate and reliable compared with the reference standard measurement for venous hemoglobin. (Postgraduate Medicine, a peer reviewed journal for physicians, compared results using both the Masimo Pronto and Hemocue 201 hemoglobin analyzers. The author concluded that the Pronto results were similar to that of the Hemocue analyzer.)

For situations in which a measurement cannot be obtained using the Masimo Pronto, or for children under two years of age who require hemoglobin measurement, the HemoCue Analyzer will continue to be used.

Here is what you will find in the revised ninth edition of the lab manual:

Training

Local Agencies have the option to designate a Local Agency trainer who, after becoming certified by ADHS Bureau of Nutrition & Physical Activity, can act as the Agency's trainer for new & existing staff. They must also undergo yearly reevaluation by ADHS BNPA to ensure their competency.

New staff members will be monitored quarterly for their first year. Subsequently, all appropriate WIC staff will undergo mandatory monitoring every 2 years and continuous monitoring throughout the year.

**Administration
of HemoCue®
Equipment**

This section includes procedures for receipt and inventory of new or loaner equipment from ADHS or directly from HemoCue®.

**Problems With
An Analyzer**

This section explains the HemoCue® 201+ System Maintenance Log to record relevant information in the event of problems with an analyzer.

Chapter 2. Safety

Universal Precautions

In 1991, the Occupational Safety and Health Administration (OSHA) published the Occupational Exposure to Bloodborne Pathogens Standard. The purpose of the standard is to minimize, if not eliminate, occupational exposure to bloodborne pathogens and, if followed, should keep you safe when you work in your lab area. The standard outlines necessary engineering and work practice controls, as well as requiring the availability and use of personal protective equipment (PPE).

One section of the standard deals with “Universal Precautions (UP).” This term is simply an approach or strategy designed to keep you safe when you work with blood or other bodily fluids. Under UP, the blood and certain bodily fluids of *all* individuals are considered potentially infectious. Standardized practices focus on treating every sample of blood as if it were disease-infected. Handle all human blood and certain human bodily fluids as if they were known to be infected with Human Immuno-deficiency Virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV) or other bloodborne pathogens. Ask your supervisor if you have further questions.

These precautions are intended to prevent the transmission of infectious bodily fluids through parenteral routes such as mucous membranes and non-intact skin.

In 2001, the standard was revised to conform to the Needlestick Safety and Prevention Act. The act directed OSHA to revise the Bloodborne Pathogens (BBP) Standard in the areas of the Exposure Control Plan with new record-keeping requirements, employee input for work practice controls and modification of definitions of engineering controls.

Personal Work Practices

To comply with the OSHA standard, a written exposure control plan must be in place at each WIC clinic/site. The plan includes a copy of local policies and procedures for employee safety and a procedure for reporting accidents. Your manual should be kept close at hand and you should adhere to all of the practices as suggested in this manual. Each local agency will develop blood-borne pathogen information and training programs for all employees.

For your personal protection, follow these guidelines:

- Get a Hepatitis B vaccination.
 - Do not allow or bring food, drinks or medication into technical work areas.
 - Do not touch your face, apply makeup or handle contact lenses while in work areas where there is a reasonable likelihood of occupational exposure.
 - Food and drink shall not be kept in refrigerators, freezers, shelves or on countertops where blood or other potentially infectious materials are present.
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Safety Continued

<p>Personal Work Practices Continued</p>	<ul style="list-style-type: none"> • The single most important means of preventing the spread of infection is hand-washing. Wash your hands: <ul style="list-style-type: none"> ✓ At the beginning and end of your shift ✓ Before a skin puncture and after removing your gloves ✓ After weighing unclothed infants ✓ After touching contaminated objects or using restroom facilities ✓ After making contact with your eyes, nose or mouth ✓ Before and after eating, drinking or handling food • Cover any break in the skin with a bandage. • Wear disposable gloves when there is a possibility of contact with bloodborne pathogens. • Use new gloves for every blood draw, even if participants are from the same family. • Take advantage of all training offered by your employer. Your employer has considered the risks of contamination and established its own standards based on "reasonable risk." • <u>Note:</u> Your local agency may determine whether masks, eye protection devices such as goggles or glasses with solid side shields, or chin length face shields, should be worn. • Usually, protective devices for eyes, nose or mouth are worn whenever splashes, spray, splatter, or droplets of blood or other potentially infectious materials may be generated and contamination may be anticipated. It is generally accepted that the HemoCue® test for hemoglobin does not splatter or spray blood. <p>Warning! If blood touches your skin or hair, wash the area with soap and water, and tell your supervisor immediately.</p> <p>If blood splashes into your eyes, flush them with water. Contact a physician.</p> <p>If you are <u>accidentally</u> stuck by a contaminated lancet, contact your supervisor. Arrange to see a licensed healthcare provider for a medical evaluation and counseling and to be tested for Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV).</p>
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Safety Continued

Worksite Protection

- Recommended Lancet for Finger Punctures (children >18 months and adults): Single-Use (needle is not able to be extended a second time) Capillary Blood Sampling Device, 2.25mm needle.
- Recommended Lancet for Heel Punctures (**infants 9-18 months and children with very small fingers**): Single-Use Capillary Blood Sampling Device, 1.8mm needle.
- Clean the work site at the beginning and end of each workday or after any contact with blood or other potentially infectious materials.
- Use a prepared bleach solution (see below) or an EPA-registered disinfectant that is effective as a tuberculocidal and kills Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV).
A list of EPA-registered disinfectants can be found at the address below. Be sure to read descriptions carefully and choose a disinfectant that is effective against TB, HIV, and HBV.
http://www.epa.gov/oppad001/list_a_sterilizer.pdf
- In order to decontaminate contaminated work surfaces. Be sure to:
 - 1) Wear clean gloves
 - 2) Completely remove all blood before applying the disinfectant
 - 3) Leave the surface wet with the disinfectant for:
 - If using bleach solution, 10 minutes
 - If using premixed solution, longest kill time listed on label
 - 4) Dispose of the infectious waste in accordance with federal, state, or local regulations (see page seven)
- EPA-registered tuberculocidal disinfectants and bleach solutions are appropriate for removing blood or other potentially infectious materials on surfaces and instruments. The Material Safety Data Sheet (MSDS) for commercial disinfectants must be posted in the clinic and all employees must be aware of its location.

Preparation and Storage of Disinfectant Solution

- Prepare a fresh bleach (5.25% sodium hypochlorite) solution daily.
 - To prepare a 10% bleach solution, mix 1 part household bleach with 9 parts tap water.
 - Store at room temperature in an opaque plastic bottle labeled "10% Bleach." The date of preparation and the expiration date should be clearly marked on the outside.
Note: The expiration date is at the end of the seventh calendar day.
 - Store out of the reach of children.
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Safety Continued

Disposal of Laboratory Waste and Supplies



- Discard all contaminated sharps, i.e.: retractable lancets & cuvettes, in special receptacles usually referred to as “sharps” containers. There are a variety of styles, and all are clearly marked with a biohazard symbol (see figure to the left). The container must be rigid, puncture-resistant, leak-proof, and disposable with a locking lid.
 - Regardless of whether or not lancets contain safety features, such as retractable blades, all used lancets and other sharp objects must be disposed of immediately in a “sharps” container. When this container is filled to the acceptable level, it must be properly disposed of as biohazardous waste.
 - Throw away other potentially infectious trash that is saturated with blood in a red, plastic biohazard bag. Find out from your supervisor how to handle biohazardous waste since it must be decontaminated before it can be disposed of in a landfill.
 - All waste that is saturated and dripping with blood must be
 - ✓ Sterilized
 - ✓ Incinerated or
 - ✓ Chemically disinfected prior to mixing and disposing with ordinary waste.
 - Waste, such as lint-free tissue, alcohol preps, gloves, bandages & wrappers, that contains blood but is not dripping, can be discarded in a regular trash bag if there are no means for biohazard waste disposal. Best Practice states it should be disposed of in a biohazard bag.
 - Keep the biohazard bag and all trash out of the reach of children.
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Chapter 3. Information About Blood Testing

Type of Blood Tests	There are many components of blood, and many tests are done for diagnostic purposes. The only blood test that will be addressed in this manual is hemoglobin.
Hemoglobin Testing	WIC staff conduct hemoglobin tests to screen and assess the participant's nutritional status. The test measures the amount of hemoglobin in the red blood cells. The hemoglobin test is performed because it is a quick screening tool for iron deficiency anemia.
Anemia	A low hemoglobin test result indicates the possibility of iron deficiency anemia. Anemia is a condition in which there are low levels of iron in the blood, with symptoms such as poor appetite, tiredness, weakness, developmental delays and learning problems present. It is the most prevalent risk factor of WIC participants. In the WIC program, a low hemoglobin level is most often treated with education and foods high in iron and Vitamin C. Referral for high-risk counseling and medical treatment may also be indicated. (Appendix A)
Anemia Cutoffs	Arizona uses the 1998 Centers for Disease Control and Prevention (CDC) Guidelines for anemia cutoffs (Appendix B). These cutoffs are also recommended by the Institute of Medicine as an acceptable reference. The cut-off values for anemia vary with altitude, age, sex, smoking status and stage of pregnancy.
Correct Values	You, as a health professional/paraprofessional, have an important responsibility for correctly assessing values which may determine whether or not a person is eligible for the WIC Program. The values also determine the type of counseling and referral a participant receives.
Training	The Local Agency Director or designated Local Agency trainer is responsible for ensuring the training, monitoring and supervision of the staff members who perform laboratory collection and analysis. Training must be adequate to meet the Clinical Laboratory Improvement Amendments (CLIA '88) regulations & follow the National Committee for Clinical Laboratory Standards (NCCLS) H4-A4 guidelines. The designated trainer must be certified and reevaluated yearly by ADHS Bureau of Nutrition & Physical Activity to ensure competency.

Information about Blood Testing Continued

Laboratory Certification

The Local Agency Director is responsible for obtaining and maintaining a Certificate of Waiver in accordance with Clinical Laboratory Improvement Amendment (CLIA) regulations. Applications can be downloaded from the Arizona Department of Health Services Website (<http://www.azdhs.gov/lab/license/clia.htm>).

- Follow the link labeled: **Applications**
- Click on: **Certificate of Waiver or Certificate of PPMP [PDF 5M]**
- Print and complete the application
- Send the completed application to:

**Office of Laboratory Services
ATTN: CLIA
250 N. 17th Avenue
Phoenix, AZ 85007
Or fax to (602) 364-0759**

Once the application is received and processed, an invoice will be sent to the local agency from the CMS (Center for Medicare and Medicaid Services) Program at the federal level. This invoice will state an official CLIA number and a fee amount. The agency must send payment for the said fee to CMS at the address stated on the invoice. Checks must be made out to CMS Laboratory Program and include the CLIA number.

The agency must obtain a valid certificate before performing any laboratory screening tests and must maintain a valid certificate at all times. The certificate is valid for two years, and the agency is responsible for applying for certificate renewal before their current certificate expires. Clinics should receive an invoice for certificate renewal from the CMS approximately 5 months before the expiration date of their current certificate, however, clinics are responsible for making sure they receive the renewal invoice and the renewal application is processed before expiration of the current certificate. Please send applications for new certificates (new clinics) 3 months before the first test will be performed.

Authorization

A Letter of Authorization, which lists the individuals qualified to obtain and analyze laboratory samples, as well as the dates when they were certified, will be maintained on file by each local agency. The letter also needs to contain dates for which certification is valid (i.e.: October 1, 20XX - September 30, 20XX).

Questions regarding CLIA certifications and Letters of Authorization can be directed to **Tanja James** at jamest@azdhs.gov or by phone at **602-364-0139**.

Information about Blood Testing Continued

Work Area

Select a work area for collection of the laboratory specimen.

An ideal work area:

- Is clean
 - Ensures client and staff safety
 - Has a surface which is smooth, free of cracks, and washable
 - Ensures patient privacy
 - Is away from noise and confusion
 - Has a chair and table
-

Hemoglobin Measuring Machines



HB 201+

The HemoCue® 201+ system is an analyzer, a portable instrument with a sliding cuvette holder and display screen. The analyzer measures the amount of hemoglobin contained in a blood sample. The measurement takes up to 60 seconds and is expressed as grams per deciliter or g/dl. After reading the sample, the value will remain displayed on the screen as long as the cuvette holder is in the measuring position. When a new sample is placed in the cuvette holder, the analyzer erases the previous value and replaces it with the new value.

The analyzer operates on AC power (AC adapter included) or 4 AA batteries. The battery symbol on the display indicates low battery power; if showing, replace the batteries as soon as possible.

Daily care of the hemoglobin analyzer is explained in Chapter 6 of this manual. Detailed cleaning instructions are also found in the HemoCue Hb 201+ Analyzer Operating Manual.

Storage of Cuvettes

- Store cuvettes at room temperature. Do not expose to any direct heat source.
 - Label the vial with the date on which it is opened.
 - Label the vial with the date on which the contents of the vial expire (vial expires 90 days after opening). Note: an unopened vial of cuvettes has a two-year shelf life from the date of manufacture.
 - Snap the vial cap closed each time a cuvette is removed. Never leave the cap partially open. The cuvettes are very sensitive to humidity and moisture. Remove one cuvette at a time for testing.
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Chapter 4. Daily Steps for Performing Hemoglobin Tests

Identify Client	Assure that the consent boxes are checked and the client or authorized representative has signed and dated the Rights & Obligations form.
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Explain Procedure	<p>Explain the procedure to the client or authorized representative in simple terms. Reassure them, especially when using an invasive hemoglobin test such as the HemoCue 201.</p> <p>Example (using the HemoCue 201):</p> <p>"I am going to make a little poke in your finger/heel to get a few drops of blood to put the blood into this little container. Then I am going to put it into this machine to find out how much iron it has in it." Be honest with him/her. If he/she asks if it may hurt, answer, "Yes, it may hurt a little."</p> <p>Don't ever say, "No, it won't hurt."</p>
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Cleanse/Glove Hands	<p>Wash hands with soap and water (or cleanse with an alcohol-based hand cleanser or hand wipes if a sink is not available). You may wait until after supplies are assembled to put on gloves.</p> <p>CHANGE GLOVES BETWEEN EVERY CLIENT!</p>
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Assemble Supplies	<p>Hands must be clean before assembling supplies. They may also be gloved if desired.</p> <ul style="list-style-type: none">• HemoCue® Analyzer• Gloves• Alcohol prep pads• Sterile lancets• Lint-free tissues/KimWipes® or Gauze pad• Closed vial of cuvettes (remove 1 at a time & recap)• Bandages (not for children under age 2)• Sharps container• Biohazard bag• 10% bleach solution or disinfectant• Soap and water, alcohol-based hand cleanser or hand wipes <p>Put gloves on after supplies are assembled if you haven't already done so.</p>
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Daily Steps for Performing Hemoglobin Tests Continued

Position Client

For infants one year of age and younger, a seated adult holds the infant over adult's shoulder or baby lies face-down across lap for heelstick.

NOTE: The heel site is recommended for infants 9-12 months of age to prevent possible bone or nerve damage in areas where there is less flesh. If a child 12-18 months of age has small fingers, it is at the staff's discretion to continue with a heelstick or to use a smaller lancet on their finger.

Children 18 months of age and older should not receive a heelstick.

For everyone else, seat client and extend arm with palm up.

♥ BE SURE THAT PUNCTURE SITE IS LOWER THAN THE HEART.

Choose Site

For infants, use either side of the plantar (bottom) surface of the heel when the baby is held over caregiver's shoulder. Never puncture the back curvature of the heel.

For everyone else, seat the participant or ask someone to help with a child. For instance, the caregiver may hold the child in his/her lap using both arms to keep the child still while you perform the procedure.

Have the client extend his/her arm with the hand lower than the heart and palm facing up. Use the middle or ring finger, but choose a finger that doesn't have a ring on it.

Warm the Site (If Necessary)

The site should not be cold, blue, swollen or calloused.

If cold, warm the site by holding it in your hands, rubbing it for a minute, or by having the participant wash their hands vigorously with warm running water and soap or gently shake her hands. The site does not need to be cleaned again with an alcohol pad.

Cleanse the Site

Cleanse the site thoroughly with an alcohol pad (unless the participant washed their hands with warm water and soap).

Wipe the site with a tissue or lint-free wipe. Be sure skin is *dry*.

Note: Pooled alcohol at the puncture site will dilute and hemolyze the blood, giving a lower reading, if the skin surface is not dried completely.

Hold the Site

For infants, position the foot below the infant's heart. Encircle the heel by wrapping the index finger around the arch and the thumb around the bottom of the heel (see figure to the left). Grasp the heel or finger firmly between your thumb and index finger using your thumb in a gentle rocking movement.

For everyone else, lightly press the finger from the closest knuckle to the tip in a rolling motion to stimulate the flow of blood to the sampling point.

WHAT NOT TO DO:

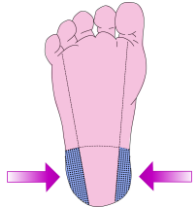
Do not touch the prepared site after cleaning. Do not "milk" the finger to speed the process. Squeezing/milking dilutes the blood and gives a false low reading.

Daily Steps for Performing Hemoglobin Tests Continued

Puncture

IMPORTANT:

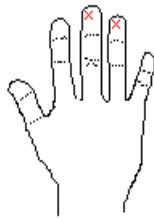
If the lancet is blade-shaped, it should be placed perpendicularly to the whorls of the fingerprint/footprint so the blood is more easily collected into the cuvette.



Create a firm surface where you are going to puncture by pulling the skin taut or tight with your index finger near the first joint of the finger on the client's hand.

For infants, 9-18 months of age or children with very small fingers, puncture only on the medial or lateral side of the bottom surface of the heel. See figure to the left.

Do not puncture the foot if there are bruises, abrasions or sloughing skin present.



For everyone else, children > 18 months of age and adults, puncture the side of the fingerpad nearest the thumb in one continuous motion using a retractable lancet. This will allow for easy blood collection. Puncturing on the side of the fingerpad is recommended and will hurt less than on top of the fingerpad since there are less nerve endings. The finger should be facing upwards upon puncture.

Fill the Cuvette



To ensure accuracy, you must wipe away the first two to three drops of blood. This will stimulate spontaneous blood flow, resulting in a better sample. If necessary, press gently again with thumb and forefinger until another drop of blood appears. Avoid "milking." **Do not touch the heel or finger at the site of puncture.**

All drops should be large enough so they "sit" on top of the heel or finger like a bead. Ensure that the drop of blood is big enough to **fill the entire cuvette, including the tip**. Touch the tip of the cuvette, pointing downward, into the middle of the blood drop so the cuvette touches the skin. Allow the cuvette to fill in one step. The cuvette will fill itself automatically. Never "top off" the cuvette if it doesn't fill in the first swipe.

Daily Steps for Performing Hemoglobin Tests Continued

Fill the Cuvette Continued

Wipe excess blood off the flat outside surfaces of the cuvette. Keep it at a 45° angle. Be careful not to touch the open-ended tip so that blood is not pulled back out of the cuvette.

Example

Using a gauze pad or lint-free wipe, "swipe" the cuvette as if you were sharpening a knife to remove any excess blood from the outside surfaces. Avoid the open "slit" of the cuvette with the gauze or wipe.

If the cuvette does not fill completely on the first try, or if air bubbles are visible, discard the cuvette, wipe the puncture site and allow a new, larger bead of blood to form before collecting into the cuvette again.

Measuring Hemoglobin Value

Pull the cuvette holder out to loading position. Turn the analyzer on by pressing and holding the On/Off button until the display is activated. The machine will run a self-test and then display three flashing dashes.

Within 10 minutes of filling the cuvette, place it in its holder and gently push the holder into the analyzer with two fingers. When closed, the analyzer will automatically start the measuring procedure and the result will appear on the display within 15-60 seconds.

Seal and Bandage Site

Place dry gauze or lint-free tissue over the puncture site and apply gentle pressure until the wound is clotted. Elevating the hand or foot above the level of the heart will help to stop the blood flow. Apply the bandage.

Note: Do not use bandages on the finger of a child less than two years of age to prevent potential ingestion and choking.

When to Run a Second Test

Occasionally, a second test must be run, such as when the displayed hemoglobin value is outside the "Nutritionist" range (Appendix B). A second sample must be taken from a different site, preferably a finger on the other hand and/or by a different user. The higher of the two hemoglobin values is entered into the AIM computer system and should also be used for referral purposes.

Example

A 6.9 g/dl reading is obtained from an 18-month-old. The second reading is 8.5 g/dl. Record 8.5 g/dl, counsel and write this higher value on the referral form to the medical provider.

Daily Steps for Performing Hemoglobin Tests Continued

Very low hemoglobin values

A very low hemoglobin level is a serious medical concern and is life-threatening. Local Agencies must establish a referral plan and train staff to ensure that all participants with confirmed very low hemoglobin values are referred for an immediate medical evaluation, either with their primary care provider or, if unavailable, at an emergency medical center. Local Agencies will work with county/agency Health Program Officers to determine clinic referral procedures. All referrals must be documented in AIM.

See Appendix A for the table of very low hemoglobin levels.

Cleanse Surface

If any blood spills on the HemoCue® Analyzer, work surfaces or skin, clean with a 10% bleach solution or disinfectant spray immediately.

Disposal of Supplies

- Throw away any paper wrappers, alcohol preps, gauze, lint-free tissues, gloves and other supplies which are not saturated and dripping with blood in a wastebasket.
 - Throw away any supplies that are saturated and dripping with blood in the red biohazard bag. If your gloves are contaminated with blood, turn the gloves inside out while taking them off and place in the biohazard bag with the other supplies.
 - Throw away all lancets and used cuvettes in the sharps container.
-

Remove Gloves and Wash Hands

Remove and discard gloves after each client and after handling contaminated waste. Clean hands with soap and water, alcohol-based hand cleanser or hand wipes if water is not available. Antiseptic hand cleanser, in conjunction with clean cloth/paper towels or antiseptic towelettes, are examples of acceptable alternatives to running water. However, when these types of alternatives are used, employees should wash their hands (or other affected areas) with soap and running water as soon as possible.

Daily Steps for Performing Hemoglobin Tests Continued

**Factors
Responsible
for Poor
Results**

Mechanical problems such as:

- Malfunctioning equipment
- Machine not clean
- Cuvettes past expiration date or left exposed to air

Poor collection technique, such as:

- Not thoroughly drying the site prior to puncture
 - Milking the site
 - Not wiping away the first two to three drops of blood
 - "Topping off" the cuvette with additional blood, resulting in air bubbles or layers in the cuvette
 - Not filling the cuvette entirely
 - Leaving the filled cuvette out of hemoglobin machine more than 10 minutes before measuring
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Chapter 5. Staff Evaluation

Policy

All staff members performing blood tests will be trained at ADHS Bureau of Nutrition & Physical Activity as a minimum requirement and authorized as competent before they perform any patient/client testing. They may also receive training at the local agency by the laboratory director or the Local Agency's designated trainer that has been certified by ADHS Bureau of Nutrition & Physical Activity.

New staff members who are authorized to perform blood testing will be monitored quarterly for their first year. Subsequently, all appropriate WIC staff will undergo mandatory monitoring every 2 years by the laboratory director or the Local Agency's designated trainer on capillary techniques and use of the HemoCue® equipment. The Staff Competency Check List will be used for monitoring (Appendix C). Continuous monitoring should also be done to ensure proper implementation of the policies and procedures regarding blood collection, analysis, and quality assurance.

Staff training will be documented in the Learning Management System (LMS).

Procedure

For agencies that have local agency-provided training, the following procedure is suggested:

1. The laboratory director or designee will observe each staff member performing each step of collection procedures as outlined on the Staff Competency Check List, Appendix C.
 2. The steps must be performed in an initial and follow-up practice session prior to clinical practice.
 3. When a step has been completed correctly, the supervisor will place a check mark (✓) in the appropriate box.
 4. When a rating of 100% is obtained, the staff member is re-evaluated in two weeks. If a rating of 100% is not obtained, the staff member will be re-evaluated at one-week intervals until the 100% rating has been obtained.
 5. Two consecutive ratings of 100% should be attained prior to authorization to perform patient/client testing.
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Chapter 6. Administration & Maintenance of HemoCue® Equipment for the Local Agencies

Equipment

The state agency has a small surplus of HemoCue analyzers. Please contact your Nutrition Services consultant to acquire additional Hb 201 analyzers.

Cuvettes will be purchased by local agencies directly from HemoCue. Please place your order with:

Joe Berthusen, Joel.t.berthusen@hemocue.com,
602-826-2027

Please specify you want a minimum of 12 months or longer
expiration date from date of delivery

Part Number: 111716 for HemoCue Microcuvettes

Order by the box. One box has 200 microcuvettes (4 vials of 50 each).

**For agencies that need smaller quantities:

Part Number: 111715 for individually wrapped HemoCue
Microcuvettes in 100-pack

Purchase of lancets are the responsibility of the local agency. See chapter two for
recommended lancet sizes.

Inventory Control - Equipment Returns or Replacements

The Local Agency administration or HemoCue® Lead will maintain current
inventory of existing analyzers at all clinics, including backup equipment not in use.
Inventory should include a minimum of serial numbers and corresponding site
locations. This will include any loaner equipment received from HemoCue® during
repairs. Any changes in inventory will be immediately reported to the State office.

Each Local Agency will have a minimum of one spare analyzer on hand at all times.
Some agencies will have more spares available based on their size. A small quantity
of analyzers will also be available for order at the state agency. Please contact your
WIC Nutrition Services consultant to order analyzers.

Quality Control

When the analyzer is turned on, it will perform a self-test. The self-test verifies the performance of the optronic unit and is performed every second hour that the machine is on. If the self-test fails, see Maintenance section below.

There is no need to perform other quality control tests, unless required by your Local Agency.

Maintenance of the Analyzer

Analyzers should be cleaned to resolve certain error codes and as needed. See the Trouble Shooting Guide in Appendix F. Local Agencies will develop policies for maintaining cleanliness of the analyzer. Cleaning instructions can also be found in the HemoCue® Hb 201+ Operating Manual.

NOTE: When the Operating Manual states to clean the analyzer/cuvette holder with alcohol, it refers to Swedish alcohol, not alcohol sold in the US. Instead of alcohol, use mild soap and water.

The cuvette holder can be cleaned with mild soap and water and left to dry completely before reinserting into the analyzer.

The exterior of the analyzer can be cleaned with mild soap and water.

Chapter 6. Administration & Maintenance of HemoCue® Equipment for the Local Agencies Continued

Chain of Support for Troubleshooting

The following chain of support should be followed when resolving challenges with the Analyzer **ONLY AFTER THE ERROR HAS BEEN ADDRESSED WITHOUT RESOLUTION**:

1st Contact – Site Supervisor

2nd Contact – Site Supervisor or Local Agency HemoCue Lead will call the state Community Services Team Administrative Assistant to report the problem. The state contact will walk the Local Agency through correcting the problem.

3rd Contact - If the problem requires additional attention the site will be instructed to contact Arizona's personal technical support with HemoCue® at 1-800-881-1611, extension 128. See Appendix D for contact names and phone numbers.

Chapter 7. Problems with the HemoCue[®] Analyzer

System Maintenance Log

The HemoCue[®] Hb 201⁺ System Maintenance Log will be maintained in a notebook in the clinic's lab area. In the event of a problem with the analyzer, all relevant information should be recorded on the Maintenance Log. See Appendix E.

Chapter 8. Glossary

Accuracy	The agreement of results with the true value for specimens measured.
Anemia	Hemoglobin concentration (or hematocrit) below the 5th percentile of the distribution of hemoglobin or hematocrit of healthy, well-nourished individuals of the same sex, age and stage of pregnancy.
Biohazard Bag/Container	A bag or container constructed of material of sufficient single thickness and strength to pass the 165-ram dropped dart impact resistant test as prescribed by STM D-1709-91 and certified by the bag manufacturer (usually red or orange and labeled "Biohazard").
Calibration	A means to determine the accuracy of an instrument by comparing it with a known standard. The HemoCue® Analyzer does a calibration “self-test” each time the analyzer is turned on.
CLIA ('88)	Clinical Laboratory Improvement Amendment of 1988 – a public law governing the operation of clinical laboratories in the U.S. and mandating that all laboratories must be regulated using the same standards regardless of the location, type or size.
Cuvette	A small transparent container in which solutions are placed for photometric analysis.
EPA-registered Disinfectant	A cleanser that is recognized by the Environmental Protection Agency as being effective against tuberculosis-causing bacteria as well as HIV & HBV. It is used to decontaminate work surfaces.
Hemoglobin	The main component of red blood cells. It serves as a vehicle for transportation of oxygen to the tissues and carbon dioxide from the tissues to the lungs.
Hemolysis	The destruction of red blood cell membrane causing release of hemoglobin into surrounding serum or plasma.
Iron Deficiency Anemia	A reduction in the number of red blood cells resulting from iron depletion as evidenced by other laboratory testing.

Glossary Continued

Lancet	A sharp metal needle or blade, often encased in plastic, which is used to puncture the skin in order to collect a blood sample. It is individually packaged to ensure sterility. OSHA requires it to be retractable or self-sheathing, disposable and used only once.
Milking	To press out, drain off, remove, or draw out blood as if by milking.
Rocking	A method used to increase blood circulation and flow to the skin puncture site by using a thumb or finger in a gentle rocking movement (lightly press the finger from the knuckle nearest the fingertip toward the end of the finger).
Sharps	A medical device or instrument such as a hypodermic needle, syringe, lancet, scalpel blade, cuvette, Pasteur pipette or broken glass that can cause a cut, puncture, or laceration.
Universal Precautions	A set of rules established by the CDC, and adopted by OSHA, to control infection from bodily fluids in the health care setting.
Standard Precautions	Guidelines that apply to blood, all bodily fluids, non-intact skin and mucous membranes; replace Universal Precautions and are to be used for the care of all patients since everyone is assumed to be infected and, therefore, a possible contaminating factor.
Vial	A small container with a lid, used especially for storing liquids.

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Chapter 10. Using the Masimo Pronto

How It Works	The Masimo Pronto measures total hemoglobin concentration of the blood. The sensor attached to the machine emits multiple lightwaves through the capillary bed of the fingertip. Changes in the light absorption can be used to measure the functional arterial oxygen saturation of the blood, from which the hemoglobin concentration can be calculated. (In a similar way the HemoCue Analyzer emits wavelengths of light to calculate total hemoglobin by the degree of light absorption in the blood droplet collected in a cuvette.)
Safety	Conducting a hemoglobin spot check is noninvasive and requires no blood. The Masimo Pronto is safe to use outside of the lab area. There is no risk of transmitting bloodborne diseases to WIC staff or other WIC participants when conducting spot checks with the Pronto device. Hand-washing procedures and antibacterial agents such as alcohol wipes are recommended to prevent the transmission of contagious diseases. The use of gloves is not necessary for the safety of staff or participants.
Choosing a Location	The selected location for using the Pronto device should be a comfortable area, free of excessive noise or distractions. It is not recommended to conduct hemoglobin spot checks with the Pronto device in a common lab area where other measurements or finger pokes are made. The sights and sounds of other participants who may be stressed or upset by lab procedures will make it more difficult to keep participants relaxed and motionless when using the Pronto.
When To Use	The Pronto replaces the HemoCue analyzer for all WIC participants at least 2 years old including women, except for circumstances when a reading cannot be obtained using the Pronto. The Pronto has been cleared for use in the clinical setting by FDA. An independent study in a peer-reviewed scientific journal concluded that the bias and standard deviation for the Pronto results were similar to that of the HemoCue analyzer.

Chapter 11. Equipment Needed

Equipment

- Equipment needed to conduct tests using the Masimo Pronto Pulse CO-Oximeter:
 - **Masimo Pronto Pulse CO-Oximeter unit**



- **RC1 Patient Cable**



One foot patient cable that connects to rainbow DCI and rainbow DC-IP

- **Rainbow DCI Digit Sensor (Adult sized, includes slender digit gauge)**



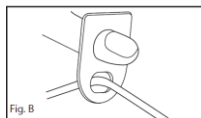
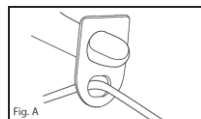
– **Rainbow DCIP Digit Sensor (Pediatric sized)**



Sensor Options for Pronto Device

- Rainbow DCI and DCIP reusable sensors are indicated for Spot Check monitoring of SpO2 and SpHb with the Pronto Device
- These sensors can be utilized on both adult and pediatric patients depending on finger size

Slender Digit Gauge



- Aids in selecting an appropriate digit for sensor application.
- Remove the gauge from the digit before sensor application

Pronto Battery Compartment



- Battery Compartment
 - Located in back panel
 - Holds 4 “AA” alkaline batteries
 - Operates up to 8 hours
 - **4 AA Alkaline or Rechargeable Batteries**

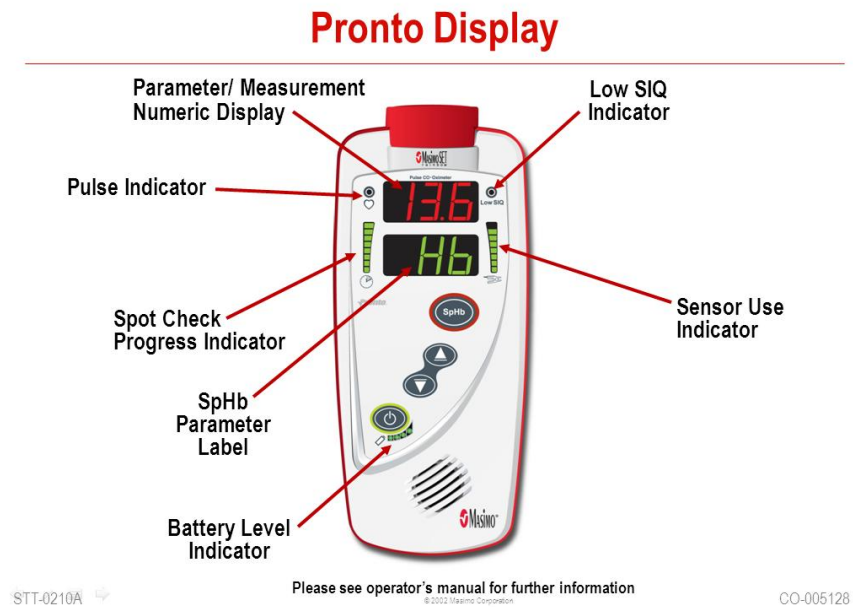


Chapter 12. Initializing the Pronto for Clinic Use

Initializing a New Device

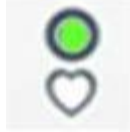
Setting up a new device:

- Open box, remove the device (enclosed in rubber casing) from box.
- Remove the device from rubber boot.
- On back of machine near the bottom is the housing for four AA batteries. Depress tab to allow battery cover to slide away. Insert batteries according to illustrated graphic guide inside battery case.
- Device will activate automatically. If machine goes to sleep, or if batteries already inserted, press green power button underneath up/down arrow buttons.



Parameter/Measurement Display

- Parameter/ Measurement Numeric Display - Displays parameter/measurement numeric values once a spot check test is complete.



Pulse Indicator

- Pulse Indicator - Flashes with patient's pulse reading (BPM) during spot check test period.



Spot Check Progress Indicator

- Spot Check Progress Indicator - Incrementally illuminates upward after a SpHb spot check has been initiated. This indicates progress towards completion of a SpHb spot check. A fully illuminated spot check progress indicator indicates a completed spot check.



Parameter/ Measurement Label Display

- Parameter/ Measurement Label Display - Displays parameter/measurement label once a spot check test is complete.



Battery Level Indicator

- Battery Level Indicator - Battery charge level is indicated by four LED indicators. All four indicators will be lit when the batteries are full, with fewer indicators being lit as the batteries lose their charge.



Low SIQ

Low SIQ Indicator

- Low SIQ Indicator - SIQ is a signal identification and confidence indicator. When this indicator illuminates, re-checking the measurement is necessary.



Sensor Use Indicator

- **Sensor Use Indicator** - This illuminates to display the approximate number of uses remaining for the attached sensor. The bottom LED will turn red when the remaining uses for the connected sensor are low. The approximate number of sensor uses remaining is displayed upon power up (if a sensor is attached) and when a sensor is connected.

Pronto Controls



STT-0210A

Please see operator's manual for further information
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CO-005128



Power On/Off Button

- **Power On/Off Button** – Powers the instrument on or off. Press the button once to power on, press and hold the Button for 2 seconds to power off.



SpHb Button

SpHb Button - Press to initiate total hemoglobin (SpHb) spot check information on display or to display a Total Hemoglobin (SpHb) spot check test. If configured, oxygen saturation (SpO2), perfusion index (PI) and pulse rate (PR) are automatically displayed. When in the configuration menu, pressing this button will confirm a menu setting and navigate to the next menu option.



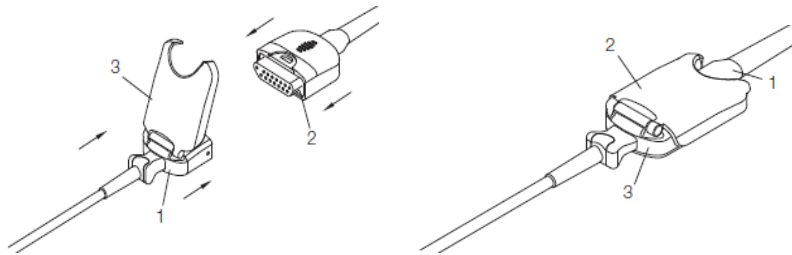
Up/Down

- Up/Down – Use the Up and Down arrow buttons to scroll between parameter or measurement spot check results. When in the configuration menu, use the Up and Down arrow buttons to scroll through menu setting options.

When initializing the device, the year, month, day, and time will need to be set.

1. Press Up and Down arrow buttons simultaneously for 5 seconds
 - a) “Yr” (year) number, press arrow to change year number to last two digits of current year
 - b) Press SpHb
 - c) “nn” (with a number below) indicates month, use arrows to enter correct month
 - d) Press SpHb
 - e) After month repeat procedure for day, hour, minute
 - f) Anytime the machine times out and returns to “00” and “Cbl” (no cable), it can be reactivated by pressing the up/down buttons
 - g) Press Up and Down arrow buttons simultaneously for 5 seconds again
 - h) Press hemoglobin (Sp/Hb) button 6 times
 - i) “Pr” pulse rate, turn “off” pulse rate by pressing up/down arrow buttons
 - j) Press SpHb
 - k) “O2” oxygen saturation, turn off oxygen saturation by pressing up/down arrow button
 - l) Press SpHb
 - m) Press SpHb button again to scroll through other options (do not make other changes without supervisor approval)

-
- 1) **Connect the RC1 Patient Cable to the Pronto device as shown in the Operator Manual.**
 - 2) **Connect the Adult or Pediatric Sensor to the RC1 Patient Cable**
 - 3) **Connecting and Disconnecting Sensor (diagram and instructions below)**



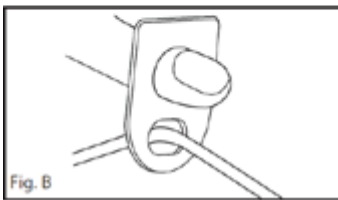
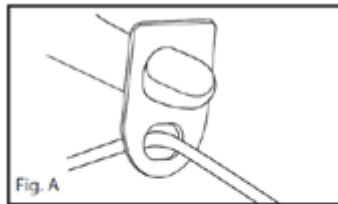
- To connect the sensor, properly orient the sensor connector (labeled 1) and insert the sensor connector completely into the patient cable connector (labeled 2).
 - Completely close the protective cover (labeled 3).
 - Check the remaining number of tests on the sensor on the device prior to the start of monitoring.
 - To disconnect the sensor, lift the protective cover (labeled 1) to gain access to the sensor connector (labeled 2).
 - Pull firmly on the sensor connector (labeled 2) to remove from the patient cable (labeled 3). To avoid damage, pull on the sensor connector, not the cable.
-

Chapter 13. Test Preparation and Performing a Reading

Test Preparation

Sensor Selection

- Measure the participant's finger size (diameter) at the cuticle, using the sensor size gauge, to determine the correct sensor size. Slide the Slender Digit Gauge circle on the digit as shown in Figure A.
- If the gauge circle stops at any point of the nail bed before the cuticle, the sensor can be used on that digit.
- If the gauge slides past the cuticle as shown in Figure B, the digit is too slender for this sensor. Select a different digit or use a pediatric / slender digit sensor on this patient.



Sensor Site Selection

Remove anything from participant's arm that can impede blood flow to the sensor site, such as restrictive garments, accessories, purses, backpacks, watches, and jewelry.

- Do not use with an anatomically abnormal finger (e.g. damaged, clubbed, deviated, etc.).
- You can use the Pronto on sites with nail polish and/or acrylic nails. Some types of nail polish may interfere with the test and prevent a reading, but it is advised to attempt tests with nail polish. Warnings in the user manual alert users that nail polish and acrylics can cause the test to fail due to low SIQ, this results in a test incomplete message.
- If the Pronto displays a result from a site with nail polish, the result is as accurate as if the site had no nail polish. If a reading fails, it does not reduce the number of tests left on the sensor.

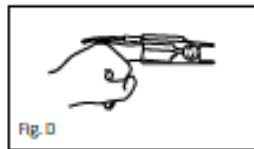
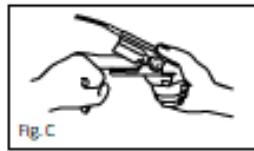
• **Hand washing or hand sanitizer for staff is recommended to reduce the transmission of contagious disease. The use of alcohol wipes on the participant's finger (or thumb as appropriate) are recommended to ensure the site is clean and dry prior to testing.**

- Select the client's testing finger in the following priority:
 - >> Non-dominant ring or middle finger
 - >> Dominant ring or middle finger
 - >> The thumb may be used on clients weighing between 22 – 110 lbs.
-

Proper Sensor Conditioning

Limit movement by securely resting client's hand and arm with sensor on a horizontal surface. Position hand below heart level to improve circulation and increase perfusion index.

- Examine the finger while placed in the sensor to ensure the emitter and detector are directly aligned on top of each other and there is no gap between the sensor and fingertip. See figures C and D.
- Make sure fingertip is inserted all the way and touching the finger stop inside the sensor (allowing long finger nails to extend beyond the finger stop).
- Ensure cable runs flat over the top of the hand lined up with the middle of the finger with no kinks or twists so the cable does not pull on the sensor. See figure E.
- Instruct client to remain still without any sensor movement. Excessive light may affect the reading. Keep the sensor positioned horizontally. **Covering the sensor with a hand or cloth will shield the sensor from excessive light. Asking caregivers to cover the hand of children may also help to limit excessive movement during the measurement.**



Tips about using the Pronto

- Once the Pronto is activated, it automatically powers off after 1 minute to spare battery power. Turn machine off when not in use to save battery power.
- Fresh batteries (alkaline, non-rechargeable) can be expected to last for approximately 8 hours of use, usually 200-250 tests per battery replacement

- Rechargeable batteries may be used but may need to be replaced more frequently than non-rechargeable alkaline batteries.
- The Pronto cannot be plugged in, it only uses battery power
- Alkaline (non-rechargeable) batteries: When the battery meter display is down to ONE bar, change the batteries. [Note: there is nothing in the manual that indicates this. This is a agencies decision.]
- Rechargeable batteries: When battery meter display is down to TWO bars, change the batteries

Tips about the sensors

- Adult and pediatric sized sensors can be used
- Slender digit guide attached to sensor for selecting appropriately sized sensor (Pediatric/Slender digit sensor is frequently used with women with slender fingers.)
- The finger of a child must be long enough and wide enough to get a reading. The thumb may be used instead for children at least 2 years old with very small fingers.
- Each sensor can be used for a specific number of tests (200, 400, or 1000), display displays the remaining number of tests when powered on
- The sensors DO NOT have a shelf life. They do not expire or become unusable if they have remaining test capacity
- The pediatric sensor has an illustration of “paper dolls” along the side of the sensor
- When the sensor has only 20 tests left the display shows TWO red bars

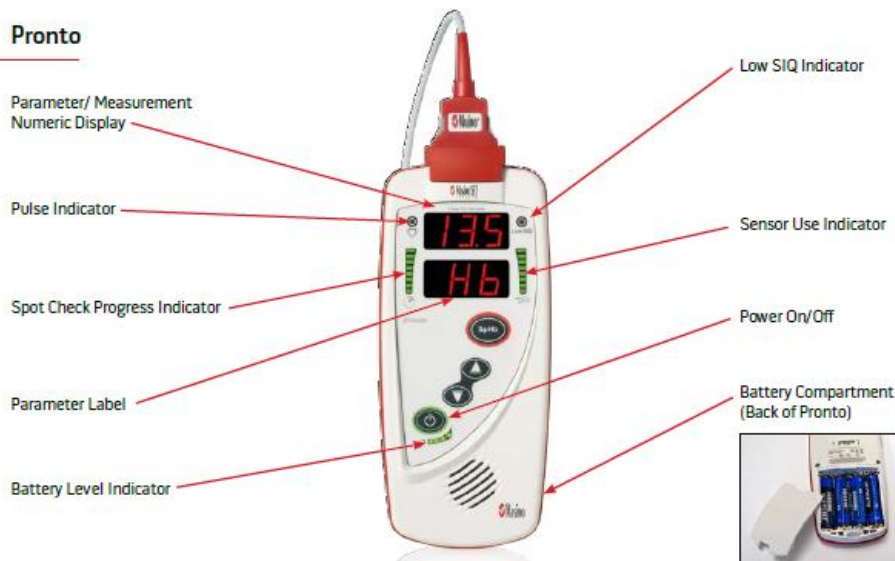
Performing a Reading

Performing a Reading - Overview

NOTE: The Pronto will be used to measure hemoglobin for all WIC participants 2 years and older, including adults.

1. Press power button to turn the Pronto on
2. Pronto goes through Self-Test
3. Pronto will display the number of sensor uses (tests) remaining on the sensor
4. When the Pronto reads SEN OFF it is ready for testing
5. Insert selected finger into the sensor to begin testing, you may use either the thumb, middle or ring finger of the non-dominant hand
6. Scrolling zeros appear and this indicates sensor initialization
7. Dashes appear which means the testing has begun
8. The letters "PI" (perfusion index) will automatically display after start up in the lower window display. The upper window display will show numerical reading of the PI.
9. Pulse indicator light will flash with each heart beat
10. It will take 1 to 3 minutes for the Pronto to acquire and display a SpHb measurement

Pronto



-
11. The Spot Check Progress indicator incrementally illuminates from bottom to top and an **audible tone** will sound when the SpHb measurement is ready to display
 12. Press SpHb button when ready to view SpHb results
 13. SpHb data will display for 5 minutes while the sensor is attached to the finger
 14. After removing the sensor from the finger, SpHb data is available for 5 minutes by depressing either the up or down arrow
-

Conducting a Successful Test

Perfusion Index (PI) is a numeric indication of the pulse strength at the measurement site

- Its numerical value ranges between 0.02% and 20%
 - Lower values indicate lower perfusion, i.e. cold hands
 - PI varies between monitoring sites and from patient to patient, as physiologic conditions vary
 - During sensor placement, use sites with higher PI readings for best results
 - Monitor the trend of the PI for changes in physiologic conditions
- To successfully conduct a test the “PI” perfusion index must measure 1.0 or greater
 - Raise hand to approximately chest level to improve circulation, perfusion index.
 - At WIC the Masimo Pronto is only used for children over 2 yrs old
 - Tests require participant to remain still until reading is completed
 - The device DOES NOT save the readings, be sure to record results immediately
 - While testing is in progress a beep will be heard that signals the reading has been taken (complete); press SpHb button after the beep to read HB value
 - If the yellow light is on, the test did not work (incomplete)
 - It will take 1-3 minutes for the Pronto to acquire an accurate SpHb spot check
 - Press SpHb Button when ready to view SpHb results or to perform additional SpHb spot checks
 - The Spot Check Progress Indicator incrementally illuminates from bottom to top and an audible tone will sound when the SpHb measurement is ready to display



- Use the Up or Down Arrow to navigate through the parameter and measurement values that have been spot checked
- SpHb data will display for 5 minutes. After 5 minutes, the data can only be obtained by downloading the data through the trend monitor or when another test is performed

Chapter 14. Troubleshooting

Interfering Factors and Troubleshooting

- Acrylic fingernails may sometimes interfere with a successful reading
 - Metallic fingernail polish may interfere with reading
 - Black or dark purple painted nails may interfere
 - Sensor inspections should be done several times a day, debris and grime block sensors (use alcohol wipe)
 - Hands dyed with henna, indocyanine green or methylene blue will interfere and make readings inaccurate
 - Changes in heart rate cause problems with testing. Choose a relaxed setting where participants are less likely to be stressed
 - 4-6% of the population have subclinical issues that will prevent a good reading (carboxyhemoglobin, other irregularities)
 - If perfusion index “PI” is less than 1.0, choose another finger
-

Difficulty or No SpHb Reading

Possible causes include:

- Interference from line frequency induced noise (electrical interference from a coiled or twisted sensor cable, for example)
- Inappropriate sensor
- Excessive motion

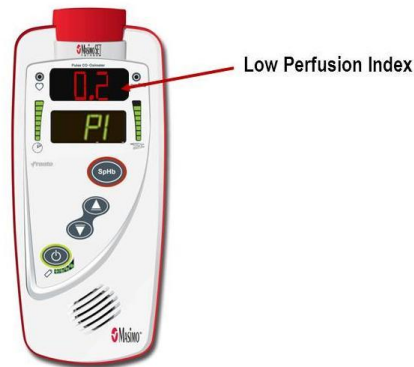
Recommendations:

- Ensure there is no coiling of the sensor cable
 - Run sensor cable straight up the back of the hand and lower arm
 - Verify use of digit gauge to select correct sensor
 - Minimize or eliminate motion at the measurement site
-

Excessive ambient or strobing light

- Shield the sensor from excessive light.
-

Low Perfusion Index



Low Perfusion Index (PI) Causes and Solutions

Causes	Improper sensor type or application Sensor applied too tightly Hypothermia (abnormally low body temperature) Vasoconstriction (narrowing of the blood vessels) Hypovolemia (decreased blood volume) Peripheral Vascular Disease
Solutions	Rule out occlusion of blood flow Assure sensor is not attached too tightly Attempt to warm the patient or sensor site Move the sensor to a better perfused site if possible (try another finger or opposite hand)

Sensor Fails to Initialize – Circulating LED's

Indication	Sensor is initializing / Determining measurement. Wait for pulse detection. Occurs whenever a spot check is initiated
-------------------	---

Causes	<p>Sensor with exposed components.</p> <p>Sensor connected to patient cable and monitor powered on before connecting sensor to patient</p> <p>Sensor adjusted to ambient light in room</p>
Solutions	<p>Always apply sensor to patient prior to connecting to patient cable</p> <p>Disconnect and reconnect single patient-use or ReSposable sensor from the patient cable after sensor application</p> <p>Shield the sensor from excessive ambient or strobing light</p>

Low Signal IQ Indicator Troubleshooting Guide

Indication	<p>The accuracy of the measurement may be compromised. The SpHb value will not display with Low Signal IQ present unless “Display Low SIQ” is enabled in the Pronto menu.</p>
Causes	<p>Improper sensor type or application</p> <p>Excessive motion or very poor perfusion</p> <p>Damaged or non-functional sensor</p> <p>Distortion of the sensor/tissue/blood flow interface – either by excessive motion or clinical care</p> <p>Ambient Light Interference</p>

Solutions	<p>Assess patient</p> <p>Rule out occlusion of blood flow</p> <p>Ensure proper sensor application and placement</p> <p>Determine if an extreme change in patient's physiology and blood flow occurred</p> <p>Apply Ambient Light Shielding</p> <p>Retest after performing above</p> <p>Number of SpHb sensor readings available will NOT be reduced when Low SIQ occurs</p>
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Chapter 15. Administration and Maintenance of the Masimo Pronto for the Local Agencies

Administration and Maintenance of Masimo Pronto for the Local Agencies

When to use HemoCue: For all WIC participants requiring hemoglobin measurement between 9 months and less than 2 years of age, the HemoCue analyzer is required.

Cleaning the Pronto

- The Pronto requires cleaning at least once daily, and should be cleaned immediately if you notice debris or grime.
- It is recommended to spray cleanser on a cloth and NOT directly on the Masimo. The outer surface of the Pronto can be cleaned with a soft cloth dampened with soap and a warm water solution.
- Other appropriate cleaning agents include commercial products such as Cidex Plus (3.4% Glutaraldehyde), 0.25% Ammonium Chloride, , 70% Isopropyl Alcohol, or by preparing a 10% Bleach solution.
- Do not allow liquids to enter the interior of the Pronto. Do not autoclave, pressure sterilize, or gas sterilize the Pronto.
- Do not soak or immerse the Pronto in any liquid. Do not use petroleum based or acetone solutions, or other harsh solvents to clean the Pronto.

Cleaning Reusable Rainbow Sensors

- Remove the sensor from the patient and disconnect from the patient cable.
- Disconnect the patient cable from the device.
- Wipe the entire sensor and / or patient cable clean with 70% Isopropyl alcohol pad.
- Allow to air dry thoroughly before returning it to operation
- To prevent damage, do not soak or immerse in any liquid solution.
- Do not attempt to sterilize by irradiation, steam, autoclave, or ethylene oxide.

Chapter 16: Other Information

- Ordering Equipment, Returns or Replacements
- Receiving a New Pronto

Ordering Equipment, Returns or Replacements

To order new Pronto machines or to order replacement sensors, please contact the Masimo customer service representative. For returns or to replace Masimo machines, please contact your Nutrition Services Consultant.

NOTE: The sensors should not be discarded with other disposable waste. When all the loaded tests have been used, sensors are considered electronic waste and should be treated like cell phones and other electronic devices. Please check with your agency about their policy for disposal of electronic waste.

For Masimo contact information, please call or email your WIC Nutrition Services Consultant.

Receiving a New Pronto

When receiving a new Masimo machine, please use the following instructions to initialize the machine for use at WIC. Features such as pulse rate and oxygen saturation are not used in the WIC setting and will be disabled to reduce the use of batteries and sensors for non-WIC purposes.

Instructions for opening a new machine:

- See Chapter 12: Initializing a New Machine

Appendices

Appendix A - Blood Work Requirements, Options and Referrals

Appendix A - Blood Work Requirements, Options and Referrals

Policy

7 CFR §246.7(e)(1) Determination of nutritional risk, and Nutrition Risk Sections of State Plan for Risk 201 for women, infants and children states that "At a minimum, . . . a hematological test for anemia such as hemoglobin...shall be performed and/or documented at certification for applicants with no other nutritional risk present. For applicants with a qualifying nutritional risk factor present at certification, such test shall be performed and/or documented within ninety (90) days of the date of certification."

The Blood Work Rule effective January 18, 2000, states that liberalizing the timeframes of blood collection is based on WIC's track record of reducing anemia rates nationally and improving coordination of services. Arizona WIC recognizes that it has one of the highest rates of anemia nationally and has enthusiastically adopted parts of the blood work rule, which will reduce barriers to service without sacrificing data collection.

Special Note

Anemia (blood) screening is part of the WIC certification process (which may be obtained via referral) and is mandatory for participation. The only time blood testing may be waived is if there is a religious objection (i.e. Christian Scientist) or a medical reason (i.e. hemophilia) or if performing the test will cause physical harm to the participant and/or staff member. In this case, one (1) month of Food Instruments may be issued and the blood test will be attempted in one month at their next WIC visit. Thus, a person may not be certified without blood work data except when religious or medical reasons exist and this must be noted in their WIC record.

If blood work data is brought from an outside source within 90 days of certification, the actual date that the blood test was performed must be entered into AIM. Do not use the date that it is being entered into AIM.

Appendix A - Blood Work Requirements, Options and Referrals

Category	Age Blood Work Required	Certification Blood Work Required	Exceptions to Certification Blood Work Required
Pregnant women	N/A	1 blood test taken during pregnancy	Prenatal women can be certified without blood work if: <ul style="list-style-type: none"> • at least one qualifying nutritional risk is present at certification and • blood test is obtained within 90 days of certification
Postpartum women	N/A	1 blood test taken 4-6 weeks after end of pregnancy	None
Breastfeeding women	N/A	For women 6-12 months postpartum, no blood test is required if 1 test was taken after end of pregnancy	For women 6-12 months postpartum, no blood test is required if 1 test was taken after end of pregnancy
Infants <9 months	Not Required	Not Required	Not Required
Infants 9 months or older	Blood work required once between 9-12 months	Blood work required for infants certifying between 9-12 months	Blood work taken between 12-13 months can be used when no other blood work is available for infant category
Children 12-24 months	Blood work required once between 12-24 months (6 months after infant test)*	Blood work required at initial certification	
Children 24-60 months	N/A	All children are required to have blood work on an annual basis unless previous blood work result demonstrated nutritional risk eligibility for low Hgb. In this case, blood work is needed every 6 months.	

*Blood work taken at or before the first birthday does not satisfy the requirement for both the infant blood work and the children's 12-24 month blood work. Separate blood work is required for each age range.

Appendix A - Blood Work Requirements, Options and Referrals

Pregnant Women

Blood work must be collected during the pregnancy.

Blood work is usually collected by WIC staff at the certification visit.

Results from an outside source (i.e. doctor's office) are also acceptable if it was collected during the pregnancy. If the results are not available at the Certification appointment, a note must be placed in the chart outlining the method and date by which the results will be reported. In the interim, the participant is placed on monthly pick-up, pending provision of blood work, for up to 60 days.

Women who are certified presumptively (with Risk 503) need to have blood work done within 90 days of certification.

They will be screened for all risks in 60 days, including anemia screening, if no other risk is found.

Postpartum & Breastfeeding Women

Blood work must be collected during the postpartum period:
Preferably within four to six weeks (30 - 45 days) after the termination of the pregnancy. Blood work is not valid if drawn before four weeks (30 days) postpartum.

The second blood test for breastfeeding women should be approximately six months postpartum. This second test is optional for women who had normal results from previous certification.

Blood work is usually collected by WIC staff at each certification visit. Results from an outside source (i.e., doctor's office) are acceptable if collected after four weeks postpartum and collected within 90 days of the certification date. This may be done only if another nutritional risk is present at the Certification appointment. The actual date that the blood test was performed must be entered into AIM. Do not use the date that it is being recorded.

Appendix A - Blood Work Requirements, Options and Referrals

Infants

Blood tests are not required for infants under nine months of age. Blood work should be collected:

- Once between 9–12 months of age, and/or
 - At the time of certification which begins after the infant has reached nine months of age.
 - By WIC staff. Results from an outside source (i.e. doctor's office) are acceptable if drawn after nine months of age for a full-term infant or after six months of age for a premature infant. A blood test before nine months of age may also be appropriate for low birth weight infants who are not fed iron-fortified formula.
 - If the blood is drawn at 12 months of age, the cutoffs used should be reflective of a one-year-old child status.
-

Children

Blood work must be done on all children at least once every 12 months after the child is 18 months old. The exception is if the blood work data was within normal limits (WNL) at or within their last certification, in which case, there may be a period of 14 months between blood tests. Children are at highest risk for anemia between 9 and 18 months of age.

- **Example:** Blood work taken at 10 months of age may be used to certify a 12 month old child. A blood test is required at the 15-18 month certification for all children.
- **Example:** A child's results were within normal limits (WNL) during the certification periods beginning at 12 months and 18 months. The test is optional at the 24-month certification.

Children 2-5 years old with low hemoglobin must have a blood test at six-month intervals. Blood work is usually collected by WIC staff at the Certification visit. Results from an outside source (i.e. doctor's office) are acceptable if drawn within 90 days of the certification date. The actual date that the blood test was performed must be entered into AIM. Do not use the date that it is being recorded. If no risk can be found at a certification, a blood test should be performed before ruling that the child is ineligible, even if the child's last result was normal.

- **Exception:** If the authorized representative waives the blood test after having the consequences explained to them, the child is then ruled ineligible.
-

Appendix A - Blood Work Requirements, Options, and Referrals

Children Continued

If the local agency has closed priorities, a blood test is recommended before placing a child on the waiting list.

Certification of a child who is new to the program will include a blood test, regardless of the age of the child.

Exception: The certification of a child who is an out-of-state transfer does not require a blood test. If a hemoglobin value from the child's most recent certification that is within normal limits is available on the Verification of Certification (VOC), that value may be entered.

Recommended Procedures

For hemoglobin results below the "Anemia" cutoff value:

The Community Nutrition Worker (CNW) will educate the participant or caregiver that WIC screens for (not diagnoses) anemia and counsels the participant on appropriate strategies to increase their iron levels.

For hemoglobin results outside the "Nutritionist" range:

If a client's hemoglobin value is outside the "Nutritionist" range for the first time, perform the procedure again. If possible, have a different person run the test on a different puncture site, such as an alternate finger or the infant's other heel. Record the higher of the two values in the AIM system.

Educate the participant or caregiver that WIC screens for (not diagnoses) anemia and since their value is outside of WIC's normal range, they will be referred to the nutritionist for further evaluation.

If the hemoglobin value remains outside of the "Nutritionist" range at their subsequent Certification, the CNW will automatically refer them to their healthcare provider. This is documented in the Referral section of the Care Plan screen in the AIM system.

Note: Poor technique may result in an abnormally low value.

Very low hemoglobin values:

A very low hemoglobin level is a serious medical concern and is life-threatening. Local Agencies must establish a referral plan and train staff to ensure that all participants with confirmed very low hemoglobin values are referred for an immediate medical evaluation, either with their primary care provider or, if unavailable, at an emergency medical center. Local Agencies will work with county/agency Health Program Officers to determine clinic referral procedures. All referrals must be documented in AIM.

Appendix A - Blood Work Requirements, Options, and Referrals

Table of Very Low Hemoglobin Values

	Hemoglobin Reading (<g/dL)
Altitude	
0-2,999 (sea level)	6.5
3000-3999	6.7
4000-4999	6.8
5000-5999	7.0
6000-6999	7.2
7000-7999	7.5
8000-8999	7.8
9000-9999	7.8
10,000 – 11,000	7.9
Cigarette Smoking – add to cut off value	
0.5 - < 1.0 pack per day	+0.3
1.0 - <2.0 packs per day	+0.5
≥2.0 packs per day	+0.7
All smokers	+0.3

Appendix A - Blood Work Requirements, Options, and Referrals

Use of 99.X codes	The 99.X codes are only to be used as placeholders in the 'Hgb' field in the Medical screen of the AIM system. They are not to be used in the height or weight fields.
99.5	<ul style="list-style-type: none"> The code 99.5 is to be used when blood work is pending. This indicates that the applicant is bringing the data from an outside source (i.e.: doctor's office). The applicant has ninety (90) days from the date of certification to bring in the data. When 99.5 is entered, only one (1) month of Food Instruments are to be issued at a time. This can occur up to three (3) times. A note must be entered into the Notes box in the Medical screen in AIM. If the applicant does not bring in the data within ninety (90) days, they are to be terminated from the WIC Program. When certifying postpartum women that are less than 4-6 weeks postpartum, a code of 99.5 should be used and one (1) month of Food Instruments should be issued. By their second postpartum WIC appointment, they will be able to have the blood work performed. All applicants (except pregnant women) who have a 99.5 code for blood work must have another qualifying risk at the time of certification in order to be eligible for WIC Program benefits. Pregnant women can be certified as presumptively eligible for sixty (60) days, without a documented nutritional risk factor while their blood work is pending; blood work must be performed and a nutritional risk must be documented within sixty (60) days of certification.
99.6	The code 99.6 is used when hemophilia (a bleeding disorder found mostly in males) or a religious reason (i.e.: Christian Scientist) are present that prevent blood from being collected. This must be documented in the Notes box in the Medical screen in AIM.
99.7	The code 99.7 is to be used when blood work is not required at that certification (see table earlier in this Appendix). If a 99.7 code is used for a C2, C3, or C4 client, then there must be a normal hemoglobin result for the client, collected and recorded within less than one year. If a 99.7 code is used for a EN or PN, there must be a normal hemoglobin result for the client, collected and recorded when the women was four (4) or more weeks postpartum. If a 99.7 code is used for a C1, PG1 or PG2 client, there must be a normal hemoglobin result for the client, collected and recorded within less than five (5) months. For pregnant women, the normal hemoglobin result on record must have been collected during the current pregnancy.
99.8	The code 99.8 is used in situations where drawing blood will create a safety hazard to the client or the WIC staff member. This is not used in the case of HIV/AIDS, since staff should always use Universal Precautions (UP; see page 2) to protect themselves. The reason this code was used must be documented in the Notes box in the Medical screen in AIM.

Appendix B – CDC Cutoffs for Anemia

Cutoff values for Hemoglobin Levels at 0-2,999 feet

Smoking Status	action	Pregnant			Breastfeeding/Post-Partum		Infant and Child	
		1st Trimester 0 – 13 weeks	2nd Trimester 14 – 26 weeks	3rd Trimester 27 + weeks	12 years to 14 years 11 months	15 years +	Infant 6 to 23 months	Child 2 to 5 years
Non-Smoker	Anemia	10.9	10.4	10.9	11.7	11.9	10.9	11.0
	Nutritionist	8.5 16.3	8.1 15.9	8.5 16.3	9.2 17.0	8.8 16.6	7.9 15.7	8.2 16.0
up to 1 pack (1-19 cigarettes)	Anemia	11.2	10.7	11.2	12.0	12.2		
	Nutritionist	8.8 16.6	8.3 16.1	8.8 16.6	9.5 17.3	9.4 17.2		
1-2 packs (20-39 cigarettes)	Anemia	11.4	10.9	11.4	12.2	12.4		
	Nutritionist	9.5 17.3	7.9 15.7	9.5 17.3	9.7 17.5	9.9 17.7		
2+ packs (40+ cigarettes)	Anemia	11.6	11.1	11.6	12.4	12.6		
	Nutritionist	10.2 18.0	7.5 15.3	10.2 18.0	9.9 17.7	10.4 18.2		

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC

Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 3,000-3,999 feet

Smoking Status	action	Pregnant			Breastfeeding/Post-Partum		Infant and Child	
		1st Trimester 0 – 13 weeks	2nd Trimester 14 – 26 weeks	3rd Trimester 27 + weeks	12 years to 14 years 11 months	15 years +	Infant 6 to 23 months	Child 2 to 5 years
Non-Smoker	Anemia	11.1	10.6	11.1	11.9	12.1	11.1	11.2
	Nutritionist	9.0 16.8	8.6 16.4	9.0 16.8	9.4 17.2	9.3 17.1	8.3 16.1	8.7 16.5
up to 1 pack (1-19 cigarettes)	Anemia	11.4	10.9	11.4	12.2	12.4		
	Nutritionist	9.3 17.1	8.8 16.6	9.3 17.1	9.7 17.5	9.8 17.6		
1-2 packs (20-39 cigarettes)	Anemia	11.6	11.1	11.6	12.4	12.6		
	Nutritionist	10.0 17.8	8.4 16.2	10.0 17.8	9.9 17.7	10.3 18.1		
2+ packs (40+ cigarettes)	Anemia	11.8	11.3	11.8	12.6	12.8		
	Nutritionist	10.7 18.5	8.0 15.8	10.7 18.5	10.1 17.9	10.8 18.6		

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC

Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 4,000-4,999 feet

Smoking Status	action	Pregnant			Breastfeeding/Post-Partum		Infant and Child	
		1st Trimester 0 – 13 weeks	2nd Trimester 14 – 26 weeks	3rd Trimester 27 + weeks	12 years to 14 years 11 months	15 years +	Infant 6 to 23 months	Child 2 to 5 years
Non-Smoker	Anemia	11.2	10.7	11.2	12.0	12.2	11.2	11.3
	Nutritionist	9.1 16.9	8.8 16.6	9.1 16.9	9.5 17.3	9.4 17.2	8.4 16.2	8.8 16.6
up to 1 pack (1-19 cigarettes)	Anemia	11.5	11.0	11.5	12.3	12.5		
	Nutritionist	9.4 17.2	9.0 16.8	9.4 17.2	9.8 17.6	9.9 17.7		
1-2 packs (20-39 cigarettes)	Anemia	11.7	11.2	11.7	12.5	12.7		
	Nutritionist	10.2 18.0	8.6 16.4	10.2 18.0	10.0 17.8	10.4 18.2		
2+ packs (40+ cigarettes)	Anemia	11.9	11.4	11.9	12.7	12.9		
	Nutritionist	10.9 18.7	8.2 16.0	10.9 18.7	10.2 18.0	10.9 18.7		

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC

Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 5,000-5,999 feet

Smoking Status	action	Pregnant			Breastfeeding/Post-Partum		Infant and Child	
		1st Trimester 0 – 13 weeks	2nd Trimester 14 – 26 weeks	3rd Trimester 27 + weeks	12 years to 14 years 11 months	15 years +	Infant 6 to 23 months	Child 2 to 5 years
Non-Smoker	Anemia	11.4	10.9	11.4	12.2	12.4	11.4	11.5
	Nutritionist	9.3 17.1	8.9 16.7	9.3 17.1	9.7 17.5	9.5 17.3	8.5 16.3	8.9 16.7
up to 1 pack (1-19 cigarettes)	Anemia	11.7	11.2	11.7	12.5	12.7		
	Nutritionist	9.6 17.4	9.2 17.0	9.6 17.4	10.0 17.8	10.1 17.9		
1-2 packs (20-39 cigarettes)	Anemia	11.9	11.4	11.9	12.7	12.9		
	Nutritionist	10.3 18.1	8.8 16.6	10.3 18.1	10.2 18.0	10.6 18.4		
2+ packs (40+ cigarettes)	Anemia	12.1	11.6	12.1	12.9	13.1		
	Nutritionist	11.0 0.0	8.4 16.2	11.0 18.8	10.4 18.2	11.1 18.9		

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC

Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 6,000-6,999 feet

Smoking Status	action	Pregnant			Breastfeeding/Post-Partum		Infant and Child	
		1st Trimester 0 – 13 weeks	2nd Trimester 14 – 26 weeks	3rd Trimester 27 + weeks	12 years to 14 years 11 months	15 years +	Infant 6 to 23 months	Child 2 to 5 years
Non-Smoker	Anemia	11.6	11.1	11.6	12.4	12.6	11.6	11.7
	Nutritionist	9.4 17.2	9.1 16.9	9.4 17.2	9.9 17.7	9.7 17.5	8.7 16.5	9.1 16.9
up to 1 pack (1-19 cigarettes)	Anemia	11.9	11.4	11.9	12.7	12.9		
	Nutritionist	9.7 17.5	9.3 17.1	9.7 17.5	10.2 18.0	10.2 18.0		
1-2 packs (20-39 cigarettes)	Anemia	12.1	11.6	12.1	12.9	13.1		
	Nutritionist	10.5 18.3	8.9 16.7	10.5 18.3	10.4 18.2	10.7 18.5		
2+ packs (40+ cigarettes)	Anemia	12.3	11.8	12.3	13.1	13.3		
	Nutritionist	11.2 19.0	8.5 16.3	11.2 19.0	10.6 18.4	11.2 19.0		

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC

Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 7,000-7,999 feet

Smoking Status	action	Pregnant			Breastfeeding/Post-Partum		Infant and Child	
		1st Trimester 0 – 13 weeks	2nd Trimester 14 – 26 weeks	3rd Trimester 27 + weeks	12 years to 14 years 11 months	15 years +	Infant 6 to 23 months	Child 2 to 5 years
Non-Smoker	Anemia	11.9	11.4	11.9	12.7	12.9	11.9	12.0
	Nutritionist	9.6 17.4	9.3 17.1	9.6 17.4	10.2 18.0	9.8 17.6	8.8 16.6	9.2 17.0
up to 1 pack (1-19 cigarettes)	Anemia	12.2	11.7	12.2	13.0	13.2		
	Nutritionist	9.9 17.7	9.5 17.3	9.9 17.7	10.5 18.3	10.4 18.2		
1-2 packs (20-39 cigarettes)	Anemia	12.4	11.9	12.4	13.2	13.4		
	Nutritionist	10.6 18.4	9.1 16.9	10.6 18.4	10.7 18.5	10.8 18.6		
2+ packs (40+ cigarettes)	Anemia	12.6	12.1	12.6	13.4	13.6		
	Nutritionist	11.3 19.1	8.7 16.5	11.3 19.1	10.9 18.7	11.3 19.1		

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC

Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Appendix C - Staff Competency Check List

Staff Competency Check List

Staff Name: _____

Completed = ✓

Not met = ✗

Supervisor: _____

Grade = # of ✓ ÷ 16 x 100 = ____%

PROCEDURE	#1	#2	#3	COMMENTS
1. Identify client				
2. Cleanse hands (can glove hands now if desired)				
3. Assemble supplies & glove hands, if not done already				
4. Position client & choose site				
5. Warm site (if necessary)				
6. Cleanse puncture site and dry				
7. Hold site firmly & pull skin taut				
8. Puncture skin (correct site and depth)				
9. Wipe off first 2-3 drops (no milking)				
10. Cuvette tip pointed down, filled in one step (no bubbles or layers)				
11. Apply pressure & bandage (if appropriate)				
12. Wipe excess blood from outside of cuvette				
13. Correctly dispose of used supplies				
14. Remove & dispose of gloves, cleanse hands				
15. Record results				
16. Clean surface				

Scores = ____ → Avg. Score ____

Staff Signature _____ Date: _____

Supervisor Signature _____ Date: _____

Appendix D – Contact List

HemoCue Technical Support

You should only contact HemoCue directly if you are instructed to do so by ADHS staff.

HemoCue Technical Support: (800) 426-7256

Arizona Department of Health Services HemoCue Equipment Support

If you are experiencing issues with HemoCue equipment, you must follow the procedures in Appendix F of this manual.

If you are unable to access the HemoCue Troubleshooting Assistance Request Form on the azwic.gov website (as detailed in Appendix F), you may call (602) 542-1886 and ask for:

1st Contact:

WIC Community Services Team Administrative Assistant



2nd Contact:

WIC Community Services Team Program Consultant



3rd Contact:

WIC Community Services Team Manager

Appendix E – HemoCue[®] Hb 201⁺ System Maintenance Log

HemoCue® Hb 201+ System Maintenance Log

Analyzer Serial Number _____

[illegible]




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Appendix F – Trouble Shooting Guide

Trouble Shooting Guide

If you are unable to resolve the problem by following this Trouble Shooting Guide, please contact HemoCue Inc. The analyzer has no serviceable parts.

Symptom	Explanation	Action
The analyzer shows an error code.	May be a temporary fault.	Turn off the analyzer and turn it on again after 30 seconds. Take a new microcuvette and repeat the measurement. If the problem continues, see specific error code below.
E00	No stable endpoint is found within the time range. 1. The cuvette is faulty. 2. The circuit board is out of order.	1a. Check the expiration date for the microcuvettes. 1b. Take a new microcuvette and repeat the measurement. 2. The analyzer needs service. Contact HemoCue, Inc.
E01–E05	1. Dirty optronic unit or faulty electronic or optronic unit.	1a. Turn off the analyzer and clean the optronic unit as described in the maintenance section. 1b. The analyzer needs service. Contact HemoCue, Inc.
E06	1. Unstable blank value The analyzer might be cold.	1. Turn off the analyzer and allow it to reach room temperature. If the problem continues, the analyzer needs service. Contact HemoCue, Inc.
E07	1. The battery power is too low.	1a. The batteries need to be replaced. Turn off the analyzer and replace the batteries, 4 type AA. 1b. Use the power adapter.
E08	The absorbance is too high. 1. An item is blocking the light in the cuvette holder.	1a. Check that the analyzer and microcuvettes are being used according to the HemoCue Hb 201 ⁺ operating manual and instructions for use. 1b. The analyzer needs service. Contact HemoCue, Inc.
E09–E30	1. Dirty optronic unit or faulty electronic or optronic unit.	1a. Turn off the analyzer and clean the optronic unit as described in the maintenance section. 1b. The analyzer needs service. Contact HemoCue, Inc.

Symptom	Explanation	Action
HHH	1. Measured value exceeds 25.6 g/dL (256 g/L, 15.9 mmol/L).	
No characters on the display	1. The analyzer is not receiving power. 2. If on battery power, the batteries need to be replaced. 3. The display is out of order.	1a. Check that the power adapter is connected to the AC power supply. 1b. Check that the power adapter is securely connected to the analyzer. 1c. Check that the cable is not damaged. 2. Turn off the analyzer and replace the batteries, 4 type AA. 3. The analyzer needs service. Contact HemoCue, Inc.
The display gives erroneous characters.	1. The display is out of order. 2. The microprocessor is out of order.	1. The analyzer needs service. Contact HemoCue, Inc. 2. The analyzer needs service. Contact HemoCue, Inc.
The display shows "  ".	1. The batteries need to be replaced. 2. If on mains power, the mains adapter or the circuit board is out of order.	1. Turn off the analyzer and replace the batteries, 4 type AA. 2a. Check that the power adapter is properly connected and working. 2b. The analyzer needs service. Contact HemoCue, Inc.
The display does not switch from "  " and "Hb" to three flashing dashes and "  " (ready for measuring).	1. The magnet in the cuvette holder may be missing. 2. The magnetic sensor is out of order.	1. The analyzer needs service. Contact HemoCue, Inc. 2. The analyzer needs service. Contact HemoCue, Inc.
Measurements on patient samples are higher or lower than anticipated.	1. Improper sampling technique. 2. The microcuvettes are beyond their expiration date, damaged or have been improperly stored. 3. The optical eye of the microcuvette is contaminated. 4. Air bubbles in the microcuvette. 5. The optronic unit is dirty. 6. The calibration of the analyzer has changed.	1. See pages 8–17 in this manual. 2. Check the expiration date and the storage conditions of the microcuvettes. Check the entire system with a commercial control. 3. Remeasure the sample with a new microcuvette. 4. Check the microcuvette for air bubbles. Remeasure the sample with a new microcuvette. 5. Clean the optronic unit as described in the maintenance section. 6. The analyzer needs service. Contact HemoCue, Inc.

Appendix G – CLIA Application for Certification

III. TYPE OF LABORATORY (Check the one most descriptive of facility type)

- | | | |
|---|---|---|
| <input type="checkbox"/> 01 Ambulance | <input type="checkbox"/> 10 Health Fair | <input type="checkbox"/> 22 Practitioner Other (Specify) |
| <input type="checkbox"/> 02 Ambulatory Surgery Center | <input type="checkbox"/> 11 Health Main. Organization | |
| <input type="checkbox"/> 03 Ancillary Testing Site
in Health Care Facility | <input type="checkbox"/> 12 Home Health Agency | <input type="checkbox"/> 23 Prison |
| <input type="checkbox"/> 04 Assisted Living Facility | <input type="checkbox"/> 13 Hospice | <input type="checkbox"/> 24 Public Health Laboratories |
| <input type="checkbox"/> 05 Blood Bank | <input type="checkbox"/> 14 Hospital | <input type="checkbox"/> 25 Rural Health Clinic |
| <input type="checkbox"/> 06 Community Clinic | <input type="checkbox"/> 15 Independent | <input type="checkbox"/> 26 School/Student Health Service |
| <input type="checkbox"/> 07 Comp. Outpatient Rehab
Facility | <input type="checkbox"/> 16 Industrial | <input type="checkbox"/> 27 Skilled Nursing Facility/
Nursing Facility |
| <input type="checkbox"/> 08 End Stage Renal Disease
Dialysis Facility | <input type="checkbox"/> 17 Insurance | <input type="checkbox"/> 28 Tissue Bank/Repositories |
| <input type="checkbox"/> 09 Federally Qualified Health
Center | <input type="checkbox"/> 18 Intermediate Care Facility for
Mentally Retarded | <input type="checkbox"/> 29 Other (Specify) |
| | <input type="checkbox"/> 19 Mobile Laboratory | |
| | <input type="checkbox"/> 20 Pharmacy | |
| | <input type="checkbox"/> 21 Physician Office | |

IV. HOURS OF LABORATORY TESTING (List times during which laboratory testing is performed in HH:MM format)

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES (must meet one of the regulatory exceptions to apply for this provision)**Are you applying for the multiple site exception?**

- ☐ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that has temporary testing sites?

- ☐ Yes ☐ No

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?

- ☐ Yes ☐ No

If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?

- ☐ Yes ☐ No

If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ☐ and attach the additional information using the same format.

NAME AND ADDRESS / LOCATION		TESTS PERFORMED / SPECIALTY / SUBSPECIALTY
Name of Laboratory or Hospital Department		
Address/Location (Number, Street, Location if applicable)		
City, State, ZIP Code	Telephone Number ()	
Name of Laboratory or Hospital Department		
Address/Location (Number, Street, Location if applicable)		
City, State, ZIP Code	Telephone Number ()	

In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING

Indicate the estimated TOTAL ANNUAL TEST volume for all waived tests performed

☐ Check if no waived tests are performed.

VII. PPM TESTING

Indicate the estimated TOTAL ANNUAL TEST volume for all PPM tests performed _____

For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the "total estimated test volume" in section VIII.

☐ Check if no PPM tests are performed

VIII. NONWAIVED TESTING (Including PPM testing)

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the information included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AOA, AABB, CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY			HEMATOLOGY		
<input type="checkbox"/> Transplant	_____		<input type="checkbox"/> Hematology	_____	
<input type="checkbox"/> Nontransplant	_____		IMMUNOHEMATOLOGY		
MICROBIOLOGY			<input type="checkbox"/> ABO Group	_____	
<input type="checkbox"/> Bacteriology	_____		& Rh Group	_____	
<input type="checkbox"/> Mycobacteriology	_____		<input type="checkbox"/> Antibody Detection	_____	
<input type="checkbox"/> Mycology	_____		(transfusion)	_____	
<input type="checkbox"/> Parasitology	_____		<input type="checkbox"/> Antibody Detection	_____	
<input type="checkbox"/> Virology	_____		(nontransfusion)	_____	
DIAGNOSTIC			<input type="checkbox"/> Antibody Identification	_____	
IMMUNOLOGY			<input type="checkbox"/> Compatibility Testing	_____	
<input type="checkbox"/> Syphilis Serology	_____		PATHOLOGY		
<input type="checkbox"/> General Immunology	_____		<input type="checkbox"/> Histopathology	_____	
CHEMISTRY			<input type="checkbox"/> Oral Pathology	_____	
<input type="checkbox"/> Routine	_____		<input type="checkbox"/> Cytology	_____	
<input type="checkbox"/> Urinalysis	_____		RADIOBIOASSAY		
<input type="checkbox"/> Endocrinology	_____		<input type="checkbox"/> Radiobioassay	_____	
<input type="checkbox"/> Toxicology	_____		CLINICAL		
			CYTOGENETICS		
			<input type="checkbox"/> Clinical Cytogenetics	_____	

TOTAL ESTIMATED ANNUAL TEST VOLUME

IX. TYPE OF CONTROL**VOLUNTARY NONPROFIT**

01 Religious Affiliation

02 Private

03 Other _____

*(Specify)***FOR PROFIT**

04 Proprietary

GOVERNMENT

05 City

06 County

07 State

08 Federal

09 Other Government

*(Specify)***X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES**

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(Sign in Ink)*

DATE

LABORATORY TEST LIST FOR WAIVED AND PPMP TESTING

Facility Name:	CLIA #
Name of Person Completing Form:	
Laboratory Director's Signature:	Date:

Please list the name of the waived test in the column on the left side and list the name of the corresponding kit and/or instrument and manufacturer in the column on the right side. **Ex- left column: whole blood glucose, right column: Bayer Diagnostics Elite Blood Glucose Meter and Test Strips.** If applicable, please check off the Provider Performed Microscopy Procedures performed.

[illegible]

PROVIDER PERFORMED MICROSCOPY PROCEDURES	*EDUCATION
Wet Mounts; including vaginal, cervical or skin specimens	
All Potassium Hydroxide (KOH) preparations	
Pinworm Exams	
Fern Test	
Post-coital direct, qualitative exams of vaginal or cervical mucous	
Urinalysis; microscopic only	
Urinalysis; non-automated with microscopy	
Urinalysis; automated with microscopy	
Two or Three glass test	
Fecal leukocyte exam	
Semen Analysis; presence and/or motility of sperm	
Nasal Smears for Eosinophils	
* Education of all persons performing PPMP tests (i.e. MD, DO, PA, NP)	